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Arizona State Board of Pharmacy

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Board Member News

Bryan Tippett EdD, vice president of academic affairs at Estrella Mountain Community College, has served the Arizona State Board of Pharmacy and the citizens of Arizona for three years from January 2004 until November 2006. His relatively short time on the Board seems longer because he has managed to make a lasting influence on the disciplinary process at the Board by encouraging and establishing more consistency in Board disciplinary actions. His influence on the disciplinary process was substantial and he always provided a valuable new perspective by serving as a sort of "devil's advocate" when discussing complex issues. He also worked diligently for two years on the Consumer Complaint Committee and provided significant input as the public member of this time-consuming committee. Despite being encouraged by the Board members and staff to seek reappointment he concluded that his schedule was too full to allow him to continue serving on the Board. His fresh perspective and sense of humor will be missed.

Chuck Dutcher, currently Board president, has been elected as chairman of District 8 at the October National Association of Boards of Pharmacy® (NABP®)/American Association of Colleges of Pharmacy District meeting in Anaheim, CA. Chuck's common sense approach and the fact that he is a full-time practicing community pharmacist should be a good fit for this important leadership position.

2007 Board Meeting Schedule

The 2007 Board meeting schedule is at *www.azpharmacy.gov/boardmeetingschedule.html,* and the first meeting is January 24-25, 2007, at the Board offices in Glendale, AZ.

National Provider Identifier (NPI) Number

The Centers for Medicare & Medicaid Services (CMS) in Washington, DC, has provided the following information: As the industry transitions to national provider identifier (NPI) compliance, remember that there is no charge to get an NPI. Providers can apply online for their NPI, free of charge, by visiting *https://nppes.cms.hhs.gov* National Plan and Provider Enumeration System (NPPES) or by calling 1-800/465-3203 to request a paper application. The CMS NPI page, located at *www.cms.hhs.gov/NationalProvIdentStand/,* is the only source for official CMS education and information on the NPI initiative; all products located on this site are available free of charge. CMS continues to urge providers to include legacy identifiers on their NPI applications, not only for Medicare but for all payors. When reporting a Medicaid number, include the associated state name. If providers have already applied for their NPI, CMS asks them to go back into the NPPES and update their information with their legacy identifiers. This information is critical for payors in the development of crosswalks to aid in the transition to the NPI.

Update: CFC and HFA Inhalers Require Physician Authorization for Exchange

On March 31, 2005, Food and Drug Administration (FDA) issued its final regulation requiring the complete phase out of commercial production of all chlorofluorocarbon (CFC) containing albuterol metered dose inhalers. (See the FDA Web site for the final ruling at *www.fda.gov/cder/mdi/mdifaqs.htm.*) The last date for commercial availability for CFC inhalers will be December 31, 2008. This policy, although approximately two years away, has caused many of the CFC manufacturers to reduce or eliminate their current production now in order to meet the final deadline. Most recently Warrick Pharmaceuticals, one of the largest CFC producers in the United States, announced its reduction and complete stoppage of production by early spring 2007. (See the FDA Web site link on this issue at *www.fda.gov/cder/drug/shortages/default.htm#Current.*)

This shift in supply of the CFC inhalers, along with the policy change from FDA, has caused a current reduction in the amount of CFC inhalers in the marketplace and made them increasingly difficult to obtain by pharmacists through wholesalers. Many wholesalers are back ordered and have been for several months. Sporadic shortages throughout the country were even widely publicized this past spring.

Many pharmacists are looking to minimize the potential problems of this shift by filling their patients' prescriptions with the alternative hydrofluoroalkane (HFA) inhalers available today. HFA inhalers are available in albuterol (Proventil® HFA, Ventolin® HFA and ProAir® HFA) and levalbuterol (Xopenex HFA™) formulations and are in supply to the pharmacist and wholesaler. All of the product alternatives are branded agents while CFC are all generic. Pharmacists should be aware, however, that HFA inhalers are classified by FDA as BX rated, meaning that they are

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and can only be ascertained by examining

FDA Issues Nationwide Alert on Counterfeit One-Touch Blood Glucose Test Strips

In mid October 2006, United States Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the US for use with various models of LifeScan, Inc, One Touch Brand Blood Glucose Monitors. The counterfeit test strips potentially could give incorrect blood glucose values; either too high or too low. At press time, no injuries have been reported to FDA.

Consumers who have the counterfeit test strips should be instructed to stop using them, replace them immediately, and contact their physicians. Consumers with questions may contact the company at 1-866/621-4855. The counterfeit test strips were distributed to pharmacies and stores nationwide – but primarily in Ohio, New York, Florida, Maryland, and Missouri – by Medical Plastic Devices, Inc, Quebec, Canada and Champion Sales, Inc, Brooklyn, NY.

The counterfeit test strips and their characteristics are:

- One Touch Basic®/Profile®
  - Lot Numbers 272894A, 2619932, or 2606340
  - Multiple Languages – English, Greek, and Portuguese text on the outer carton
  - Limited to 50-Count One Touch (Basic/Profile) Test Strip packages
- One Touch Ultra®
  - Lot Number 2691191
  - Multiple Languages – English and French text on the outer carton
  - Limited to 50-Count One Touch Ultra Test Strip packages

LifeScan has alerted the public via a press release and has notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advises customers to contact their original source of supply for restitution. For more information, visit *www.GenuineOneTouch.com.*

New DEA Number Assignments; Updated DEA Practitioner's Manual Released

In early November 2006, Drug Enforcement Administration announced that due to the large Type A (Practitioner) registrant population, the initial alpha letter "B" has been exhausted. The Agency, therefore, has begun using the new alpha letter "F" as the initial character for all new Type A (Practitioner) registrations. For more information, visit *www.deadiversion.usdoj.gov/drugreg/reg_apps/new_reg_number110906.htm.*

Additionally, in August 2006, the Agency released the Practitioner's Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition. The Manual, prepared by the Agency's Office of Diversion Control, is designed to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession. The Manual can be accessed at *www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual090506.pdf.*

Optimizing Computer Systems for Medication Safety

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Computers that are used by pharmacists are essential professional tools that can increase staff efficiency and support effective drug utilization review and therapeutic drug monitoring. At the same time, pharmacists must not place sole reliance on this tool as a means to protect patients from drug-induced harm.

Many of today's computer order-entry systems provide vendor-defined and user-defined alerts that remind or warn staff about potential drug-related problems during order entry. The Institute for Safe Medication Practices (ISMP) often recommends these alerts as a way to inform staff about potential errors. However, pharmacists have expressed concern that the sheer number of warnings that appear on the screen during order entry can be overwhelming and slow the process. In many cases, clinically insignificant warnings are as likely to appear as those that are vital. As a result, staff may inadvertently bypass critical warnings, especially when the workload is high. This is easy to do with many systems.

In an informal survey on computer systems, we found that all too often it simply requires striking the "enter" key to bypass an alert, even those that could prevent serious or fatal errors. Also, if the system forces a response to the warning, practitioners who feel pressured to rush through order entry may select the first reason listed on the screen instead of appropriately addressing the issue. Another issue is that when pharmacists are properly alerted to a potential allergic reaction or harmful drug interaction, they may erroneously assume that the prescriber is already aware of the problem and fail to alert the prescriber directly.

When practitioners become accustomed to receiving unimportant or clinically irrelevant warnings they often ignore these "false alarms," or turn them off, at least mentally. Here are some strategies that can be used to optimize the effectiveness of alerts and minimize the possibility of overlooking the more significant ones:

- Use a tiered system for interactive warnings that allows staff to view and consider possible warnings but easily bypass less serious issues, if appropriate. Require a text entry to describe the response to more significant alerts.

- Pharmacies should assign pharmacists who enter orders the task of noting any warnings that they feel are not clinically significant. The severity level of certain alerts may need to be changed in order not to "overload" the pharmacist. However, wholesale changing of severity levels according to vendor specifications should be done with caution. Check with your vendor to fully understand how they assign severity levels before making any changes to ensure you are not missing warnings you deem to be critical.
- Make significant alerts as visible as possible. Some systems may allow large screen fonts in a contrasting color, flashing messages, sounds, or other means of distinguishing the alert.
- Maximize a system's capabilities whenever possible by incorporating serious error-prone situations that have been reported in this column as well as other publications.
- Review non-interactive pop-up messages on an ongoing basis, such as the ones we suggest for avoiding drug name mix-ups. Delete any that are no longer applicable.
- Apply auxiliary labels to drug packages and storage shelves to warn about unclear or confusing labeling and packaging, instead of using certain messages in the computer system.
- Consider printing warnings on drug labels or medication storage areas instead of building alerts into the order entry process. For example, print "Topical or External Use Only" warnings on drug labels for all drugs that can be administered safely only by this route.
- Many systems are capable of providing reports about all warnings that have been overridden. Assign a clinician or manager to review the report daily and periodically identify those warnings that are continually overridden. Share report results with staff members before changes are made to the computer system. Consider focusing on one or two common but critically important warnings to monitor the effectiveness of the computer's alert system and the response to the alert.

Revised Coumadin Labeling and Medication Guide

FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin®, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern.

Information about all currently approved Medication Guides is available at *www.fda.gov/cder/Offices/ODS/medication_guides.htm.*

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit *www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin.*

FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatments

The Federal Trade Commission (FTC) and FDA, working with government agencies in Mexico and Canada, have launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign has so far included approximately 180 warning letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web surf for "hidden traps" by the International Consumer Protection and Enforcement Network, an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer, and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products. Using the results of the Internet sweep, FTC sent warning letters for deceptive ads to 84 domestic and seven Canadian Web sites targeting US consumers, and referred an additional 21 sites to foreign governments. About a quarter of the firms have already changed their claims or removed their pages from the Internet, and several others are in contact with FTC.

FTC also announced a new consumer education campaign to teach consumers how to avoid phony diabetes cures. The materials encourage consumers to "Be smart, be skeptical!" and will be available in English, Spanish, and French. One component is a "teaser" Web site available at *http://wemarket4u.net/glucobate/index.html.* At first glance, the site appears to be advertising a cure for diabetes called Glucobate, but when consumers click for more information on ordering the product, it reveals information about avoiding ads for phony cure-alls in the future. The new education materials, including a bookmark and consumer alert, were introduced to coincide for Diabetes Awareness Month in November.

FDA Implements Strategy for Phony Dietary Supplement Claims

FDA has developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy was designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. One emphasis is on claims aimed at patients with serious diseases such as cancer and diabetes. Over an approximate 12-month time frame, the Agency has sent more than 100 warning letters and other advisories to Internet firms and has seized products at one firm. In addition, the Agency maintains special Web sites, in English and Spanish, which amplify the Agency's counsel to consumers to check with their doctor, nurse or pharmacist before trying any new health care product. These materials cover a broad range of subjects of special interest to patients with diabetes (*www.fda.gov/diabetes/; www.fda.gov/diabetes/pills.html; www.fda.gov/opacom/lowlit/diabetes.html; www.fda.gov/opacom/lowlit/sdiabetes.html*), as well as more general health care information.

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not substitutable for each other without physician authorization. Switching inhalers without physician authorization is illegal by Arizona state law and can result in potential liability by the pharmacist. The Board will be monitoring for appropriate physician authorization during this transition period and warnings may be given if there is failure to obtain the physician authorization.

In summary, there are no generic HFA alternatives to albuterol CFC on the market today. Due to the BX rating of CFC for HFA and between all the HFAs, pharmacists are required by law to ensure all switches receive authorization from the prescribing physician.

DEA Rules on Issuing Multiple Schedule II Rx's for the Same Drug to a Patient

Drug Enforcement Administration (**DEA**) has recently published several items that could be of interest to health care practitioners in Arizona. These items may be found on the **DEA** Diversion Web site *www.diversion.usdoj.gov/.*

In the *Federal Register* dated September 6, 2006, Volume 71, Number 172, (Pages 52724-52726), **DEA** published a proposed rule dealing with the issuance of multiple prescriptions for Schedule II controlled substances. The notice may be found at *www.diversion.usdoj.gov/fed_regs/rules/2006/fr0906.htm.* By issuing the proposed rule, **DEA** is returning to a previous interpretation of its statutes that existed for years until a very different interpretation was published about two years ago. The new interpretation will allow prescribers to issue, where appropriate, multiple Schedule II prescriptions to a patient on one office visit. **Please note that this is a proposed rule.** The comment period was open until November 6, 2006. After reviewing the comments received, **DEA** will make a decision about making the rule permanent. The wording of the proposed rule changes are as follows:

21 CFR Sec. 1306.12 Refilling prescriptions; issuance of multiple prescriptions.

(a) The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

(b)(1) An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:

(i) The individual practitioner properly determines there is a legitimate medical purpose for the patient to be prescribed that controlled substance and the individual practitioner is acting in the usual course of professional practice;

(ii) The individual practitioner writes instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill the prescription;

(iii) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;

(iv) The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and

(v) The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.

(2) Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Sec. 1306.14 Labeling of substances and filling of prescriptions.

(e) Where a prescription that has been prepared in accordance with Sec. 1306.12(b) contains instructions from the prescribing practitioner indicating that the prescription shall not be filled until a certain date, no pharmacist may fill the prescription before that date.

Please note that this is a proposed change to **DEA** rules and will not be permanent until **DEA** makes that decision sometime in the future. Meanwhile, the Board encourages prescribers and pharmacists to continue to care for their patients appropriately. Most prescribers disagreed with the **DEA**'s previous position that multiple Schedule II prescriptions were "tantamount to a refill" and continued to treat patients effectively, including the issuance of multiple Schedule II prescriptions when appropriate. This proposed rule shows that the policy makers at **DEA** have changed their opinions and may do so again. Please continue to treat patients effectively and appropriately during this interim period until the proposed regulations become final. The most important concept to keep in mind is the mandate that the medication be prescribed and dispensed "for a legitimate medical purpose." A health care practitioner that prescribes, dispenses, or administers controlled substances for a legitimate medical purpose should not experience any problems with law enforcement agencies. Legitimate medical purpose is currently and properly defined by practitioners and the licensing boards, not by law enforcement agencies, and if you act in the best interests of the patient, there should be no problems.

One other new publication from **DEA** that may be of interest to prescribers and pharmacists alike is the revised version of the Practitioner's Manual. This was issued in August of this year, so it contains current information about the laws, regulations, and policy for prescribers. This Manual, as well as other practice oriented manuals, may be found at *www.deadiversion.usdoj.gov/pubs/manuals/index.html.*

Diabetic Test Strips Scam

A group suspected to be from Nigeria has been contacting pharmacies in Arizona with a scheme to defraud the pharmacies by utilizing the text telephone system (TTY) or telephone deaf device (TDD) system and FedEx to call in requests to order and have the products sent to Africa. Stolen Discover® cards are always used to order the products and a few pharmacies have ended up "on the hook" for several thousand dollars.

Disciplinary Actions – Board of Pharmacy (Actions Since October 2006 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

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Pharmacists

Albert, Rory (S06403) – Two-year probation, Cannot serve as preceptor or pharmacist-in-charge (PIC). Effective November 10, 2006.

Breeding, Anthony (I07859, S15856) – Five-year probation imposed while an intern. Effective November 10, 2006.

Brophy, William (S12173) – Three-year probation. Cannot serve as preceptor or PIC. Effective September 26, 2006.

Dalkin, Thomas (S12296) – Suspension six months – one year, followed by five-year Probation. Cannot serve as preceptor or PIC. Effective November 10, 2006.

Denick, Kevin (S08392) – License reinstated with five-year probation. Cannot serve as preceptor or PIC. May not work as the only pharmacist on duty. Effective November 10, 2006.

Lieb, Karen (S08619) – License reinstated with probation. Effective November 10, 2006.

Maher, Mustafa (S11070) – Suspension terminated. Four-year probation imposed. Effective November 10, 2006.

O'Neil, James (S06570) – Five-year probation. Cannot serve as preceptor or PIC. Effective September 26, 2006.

Osborn, Daniel (S12833) – Probation terminated. Effective September 20, 2006.

Pillon, Richard (S06697) – Additional two years probation. Cannot serve as preceptor or PIC. May not work as the only pharmacist on duty. Effective September 26, 2006.

Ray, Jonathan Corey (S13139) – Revoked. Effective October 18, 2006.

Roberson, Brett (S12887) – Suspended six months – one year, followed by four to four-and-a-half years probation. Cannot serve as preceptor or PIC. Effective June 17, 2006.

Westley, Craig (S12360) – Probation terminated. Effective September 20, 2006.

Pharmacy Technicians

Bates, Pamela (T06565) – Revoked. Effective September 26, 2006.

Espino, Edward (T07615) – Revoked. Effective October 18, 2006.

Jordan (Sudkamp), Denise (T00306) – Revocation Stayed. One-year probation. Effective September 26, 2006.

Lodge, Ryan (T05821) – Revoked. Effective September 26, 2006.

McKinney, Jeffrey (T08347) – Revoked. Effective November 10, 2006.

Miles, Samantha (T06312) – Revoked. Effective September 26, 2006.

Oritz, Diane (T01404) – Revoked. Effective November 10, 2006.

Provo, Brandee (T09151) – Revoked. Effective September 26, 2006.

Rocha, Guadalupe (T08653) – Revoked. Effective September 26, 2006.

Savage, Randy (T05747) – Revoked. Effective October 18, 2006.

Serna, Bernadette (T09676) – Revoked. Effective September 26, 2006.

Disciplinary Actions – Other Health Care Licensing Boards

Castillo, Robert Diaz (MD 11036) – *Interim consent pending investigation* – Respondent shall not practice clinical medicine/medicine involving direct patient care. Respondent is prohibited from prescribing any treatment, including prescription medication. Effective September 19, 2006.

Denicole, Michael (DO 2103) – Five years probation. Respondent shall not practice medicine until completion of in-patient evaluation/treatment. Effective May 8, 2006.

Ghaffari, Dariush (MD 21840) – License surrendered. Effective August 11, 2006.

Goldwasser, Harry (MD 20842) – *Interim consent pending investigation* – Respondent shall not practice clinical medicine/medicine involving direct patient care. Respondent is prohibited from prescribing any treatment, including prescription medication. Effective October 5, 2006.

Hemphill, Mark R. (MD 24566) – *Interim consent pending investigation* – Respondent shall not practice clinical medicine/medicine involving direct patient care. Respondent is prohibited from prescribing any treatment, including prescription medication. Effective September 29, 2006.

Hsu, Unen Du (MD 8373) – *Interim consent pending investigation* – Respondent shall not prescribe scheduled substances. Effective October 26, 2006.

Ibrahim, Wahid (MD 30413) – Revoked. Effective August 11, 2006.

Kennedy, Ethan O. (DO 3123) – Probation term No. 1 amended. Respondent allowed to prescribe cough syrup containing hydrocodone or codeine. Effective October 18, 2006.

Mitchell, Howard L. (MD 30004) – Revoked. Effective August 11, 2006.

O'Beirne, Edward (PA) – Voluntarily surrendered DEA license MO-0192396. Effective August 17, 2006.

Robrock, James L. (MD 16209) – *Interim consent pending investigation* – Respondent shall not practice clinical medicine/medicine involving direct patient care. Respondent is prohibited from prescribing any treatment, including prescription medication. Effective October 5, 2006.

Tillinghast, James (MD 14418) – *Interim consent pending investigation* – Respondent shall not practice clinical medicine/medicine involving direct patient care. Respondent is prohibited from prescribing any treatment, including prescription medication. Effective August 15, 2006.

Yarusso, James (MD 31732) – Inactive with cause. Effective September 18, 2006.

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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